

(as specified in § 409.42(b)) in consultation with agency professional personnel at least every 60 days or more frequently when there is a—

- (i) Beneficiary elected transfer;
- (ii) Significant change in condition resulting in a change in the case-mix assignment; or
- (iii) Discharge and return to the same HHA during the 60-day episode.

(2) Each review of a beneficiary's plan of care must contain the signature of the physician who reviewed it and the date of review.

(f) *Termination of the plan of care.* The plan of care is considered to be terminated if the beneficiary does not receive at least one covered skilled nursing, physical therapy, speech-language pathology services, or occupational therapy visit in a 60-day period unless the physician documents that the interval without such care is appropriate to the treatment of the beneficiary's illness or injury.

[59 FR 65494, Dec. 20, 1994, as amended at 65 FR 41210, July 3, 2000]

§ 409.44 Skilled services requirements.

(a) *General.* The intermediary's decision on whether care is reasonable and necessary is based on information provided on the forms and in the medical record concerning the unique medical condition of the individual beneficiary. A coverage denial is not made solely on the basis of the reviewer's general inferences about patients with similar diagnoses or on data related to utilization generally but is based upon objective clinical evidence regarding the beneficiary's individual need for care.

(b) *Skilled nursing care.* (1) Skilled nursing care consists of those services that must, under State law, be performed by a registered nurse, or practical (vocational) nurse, as defined in § 484.4 of this chapter, and meet the criteria for skilled nursing services specified in § 409.32. See § 409.33(a) and (b) for a description of skilled nursing services and examples of them.

(i) In determining whether a service requires the skill of a licensed nurse, consideration must be given to the inherent complexity of the service, the condition of the beneficiary, and accepted standards of medical and nursing practice.

(ii) If the nature of a service is such that it can safely and effectively be performed by the average nonmedical person without direct supervision of a licensed nurse, the service cannot be regarded as a skilled nursing service.

(iii) The fact that a skilled nursing service can be or is taught to the beneficiary or to the beneficiary's family or friends does not negate the skilled aspect of the service when performed by the nurse.

(iv) If the service could be performed by the average nonmedical person, the absence of a competent person to perform it does not cause it to be a skilled nursing service.

(2) The skilled nursing care must be provided on a part-time or intermittent basis.

(3) The skilled nursing services must be reasonable and necessary for the treatment of the illness or injury.

(i) To be considered reasonable and necessary, the services must be consistent with the nature and severity of the beneficiary's illness or injury, his or her particular medical needs, and accepted standards of medical and nursing practice.

(ii) The skilled nursing care provided to the beneficiary must be reasonable within the context of the beneficiary's condition.

(iii) The determination of whether skilled nursing care is reasonable and necessary must be based solely upon the beneficiary's unique condition and individual needs, without regard to whether the illness or injury is acute, chronic, terminal, or expected to last a long time.

(c) *Physical therapy, speech-language pathology services, and occupational therapy.* To be covered, physical therapy, speech-language pathology services, and occupational therapy must satisfy the criteria in paragraphs (c)(1) through (4) of this section. Occupational therapy services initially qualify for home health coverage only if they are part of a plan of care that also includes intermittent skilled nursing care, physical therapy, or speech-language pathology services as follows:

(1) Speech-language pathology services and physical or occupational therapy services must relate directly and specifically to a treatment regimen

(established by the physician, after any needed consultation with the qualified therapist) that is designed to treat the beneficiary's illness or injury. Services related to activities for the general physical welfare of beneficiaries (for example, exercises to promote overall fitness) do not constitute physical therapy, occupational therapy, or speech-language pathology services for Medicare purposes.

(2) Physical and occupational therapy and speech-language pathology services must be reasonable and necessary. To be considered reasonable and necessary, the following conditions must be met:

(i) The services must be considered under accepted standards of medical practice to be a specific, safe, and effective treatment for the beneficiary's condition.

(ii) The services must be of such a level of complexity and sophistication or the condition of the beneficiary must be such that the services required can safely and effectively be performed only by a qualified physical therapist or by a qualified physical therapy assistant under the supervision of a qualified physical therapist, by a qualified speech-language pathologist, or by a qualified occupational therapist or a qualified occupational therapy assistant under the supervision of a qualified occupational therapist (as defined in § 484.4 of this chapter). Services that do not require the performance or supervision of a physical therapist or an occupational therapist are not considered reasonable or necessary physical therapy or occupational therapy services, even if they are performed by or supervised by a physical therapist or occupational therapist. Services that do not require the skills of a speech-language pathologist are not considered to be reasonable and necessary speech-language pathology services even if they are performed by or supervised by a speech-language pathologist.

(iii) There must be an expectation that the beneficiary's condition will improve materially in a reasonable (and generally predictable) period of time based on the physician's assessment of the beneficiary's restoration potential and unique medical condition, or the services must be necessary

to establish a safe and effective maintenance program required in connection with a specific disease, or the skills of a therapist must be necessary to perform a safe and effective maintenance program. If the services are for the establishment of a maintenance program, they may include the design of the program, the instruction of the beneficiary, family, or home health aides, and the necessary infrequent reevaluations of the beneficiary and the program to the degree that the specialized knowledge and judgment of a physical therapist, speech-language pathologist, or occupational therapist is required.

(iv) The amount, frequency, and duration of the services must be reasonable.

[59 FR 65494, Dec. 20, 1994]

§ 409.45 Dependent services requirements.

(a) *General.* Services discussed in paragraphs (b) through (g) of this section may be covered only if the beneficiary needs skilled nursing care on an intermittent basis, as described in § 409.44(b); physical therapy or speech-language pathology services as described in § 409.44(c); or has a continuing need for occupational therapy services as described in § 409.44(c) if the beneficiary's eligibility for home health services has been established by virtue of a prior need for intermittent skilled nursing care, speech-language pathology services, or physical therapy in the current or prior certification period; and otherwise meets the qualifying criteria (confined to the home, under the care of a physician, in need of skilled services, and under a plan of care) specified in § 409.42. Home health coverage is not available for services furnished to a beneficiary who is no longer in need of one of the qualifying skilled services specified in this paragraph. Therefore, dependent services furnished after the final qualifying skilled service are not covered, except when the dependent service was not followed by a qualifying skilled service as a result of the unexpected inpatient admission or death of the beneficiary, or due to some other unanticipated event.